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14. ABSTRACT

 Purpose: To determine the efficacy of self-treatment with Pulsed Electromagnetic Frequency (PEMF) therapy, delivered via the Biomodulator™, in reducing chronic low back pain (LBP) symptoms and analgesic use in military service members (SMs) when compared to usual care (UC) alone. Secondarily, to determine whether treatment produces variability in secondary biopsychosocial variables often associated with chronic pain.

Design: Prospective, randomized pilot study with repeated measures at baseline, post-treatment (4 weeks), and follow-up (8 weeks) for two groups

Methods: Participants were randomized to receive: (1) UC or (2) UC + PEMF. Usual care consisted of medication management and LBP education. Those in the UC + PEMF group self-administered 30-minute Biomodulator treatments three times per week for 4 weeks. Participants completed questionnaires at baseline, post-treatment, and 1 month follow-up assessing pain; medication use; depression, anxiety, post-traumatic stress symptom severity; sleep quality, disability; mental and physical health related quality of life (HrQoL); social support and social conflict.

Sample: Convenience sample of 75 SMs

Analysis: Descriptive Statistics; 2 X 3 ANOVA (α = .05)

Findings: The HrQoL Mental Component Score and Physical Component Score 2 x 3 (group x time) interactions were significant: $F_{(2, 104)} = 4.20$, $p = .018$ ($\eta2 = .075$) and $F_{(2, 104)} = 4.75$, $p = .011$ ($\eta2 = .084$), respectively; as was anxiety symptom severity: $F_{(2, 104)} = 5.28$, $p = .007$ ($\eta2 = .092$).

Implications for Military Nursing: Self-treatment with PEMF in conjunction with UC demonstrated improvements in SMs' overall physical HrQoL with expected, yet statistically nonsignificant improvements in reported pain, pain medication use, and LBP-related disability. There were significant between group differences in anxiety symptom severity with higher symptoms reported by the UC + PEMF group and lower symptoms and poorer mental HrQoL reported by the UC only group, a surprising finding that warrants further investigation.

15. SUBJECT TERMS

Biomodulator, Pulsed Electromagnetic Frequency, Chronic Low Back Pain

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Effectiveness of Biomodulator in treating
chronic pain and reducing medications

1 March 2012 – 31 August 2016

The Geneva Foundation

917 Pacific Ave, Suite 600, Tacoma WA
98402

Principal Investigator (PI) Military Contact Information

Duty Title

Address

Telephone

Mobile
Telephone

E-mail Address

PI Home Contact Information

Address

Telephone

Mobile
Telephone
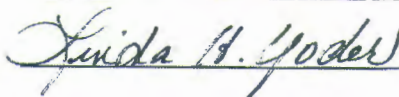
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Mentor Signature   _Linda H. Yoder_   Date _12/7/2016_

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Abstract

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TSNRP Research Priorities that Study or Project Addresses

Primary Priority

Force Health Protection:	☒ Fit and ready force ☐ Deploy with and care for the warrior ☐ Care for all entrusted to our care
Nursing Competencies and Practice:	☐ Patient outcomes ☐ Quality and safety ☐ Translate research into practice/evidence-based practice ☐ Clinical excellence ☐ Knowledge management ☐ Education and training
Leadership, Ethics, and Mentoring:	☐ Health policy ☐ Recruitment and retention ☐ Preparing tomorrow's leaders ☐ Care of the caregiver
Other:	☒ Army Nurse Corps High Priority Research Topic: Evaluation of CAM for Pain and Well-Being

Secondary Priority

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Other:	☒ Office of the Army Surgeon General Army Pain Task Force Research Priorities

Progress towards Achievement of Specific Aims of the Study or Project

Background

    In the United States Armed Services, mechanical low back pain (LBP) is a significant public health problem that affects mission readiness and the health and fitness of military service members (SM). It is one of the principal reasons SMs seek care in the deployed setting; and between 2000-2009, it was the primary diagnosis for over 7 million ambulatory care visits and 31,625 hospitalizations.[1] Current estimates are that approximately 25% of people with acute LBP experience recurrent episodes over the course of a year and 7-10% progress to a chronic state.[2,3] In 2011, the Army Pain Task Force reported that military healthcare providers over-prescribed opioid analgesic medications for the treatment of chronic pain. This trend resulted in higher rates of opioid abuse, misuse and addiction as well as to the development of performance-altering side effects among SMs.[4] Therefore as we gain a better understanding of the physiologic basis of chronic pain perception and transmission, exploring alternatives to traditional pharmacologic pain management and documenting treatment effectiveness is the next logical step. The Biomodulator is a novel hand-held device approved by the Federal Drug Administration that delivers Pulsed Electromagnetic Frequency (PEMF) therapy for the symptomatic relief and management of chronic, intractable pain and post-traumatic pain.[5] To date, no rigorous studies were found that demonstrate its efficacy in the treatment of chronic LBP symptoms in a military population.

Aims

    Therefore, the primary aim of this prospective, randomized, two group pilot study was to determine whether Usual Care (medication management + LBP education) along with adjunctive Pulsed Electromagnetic Frequency (PEMF) therapy, delivered via the Biomodulator™ device, was more effective than Usual Care (UC) alone in reducing chronic LBP symptoms and analgesic medication use in military SMs. Aim 2 was to determine whether UC + PEMF produced any variability, beyond UC alone, in the biopsychosocial secondary sequelae that often accompany chronic pain. The biopsychosocial phenomena of interest included: depression, anxiety, and post-traumatic stress symptom severity, sleep quality, LBP-related disability, mental and physical health related quality of life (HrQoL); and social support and social conflict. Finally, Aim 3 of this pilot study was to assess the feasibility of the research design and the acceptability of the treatment interventions to guide the development of a future full-scale study. What follows is a description of the study sample, the posited research questions relative to these specific aims and the study findings.

Sample

    Seventy-five (N =75) military SMs with a three month or greater history of chronic persistent or intermittent LBP symptoms were recruited for study participation from a large military treatment facility in the southern United States. The mean age of participants was 38 (SD = 8.9) with an age range from 19 to 60. Sixty-nine percent of sample participants were male (n = 52), 78.7% (n = 59) married, and the majority (n = 46) identified their race or ethnicity as Caucasian followed by 18.7% (n = 14) identifying as Hispanic. With regard to military rank, 53.3% (n = 40) of the sample were enlisted SMs and 38.7% (n = 29) were officers. Table 1 describes key LBP indicators characteristics regarding duration and intensity of pain symptoms, interference with sleep and work, and opioid medication prescription history at baseline for the sample dependent

on their treatment group allocation. When asked about their prior use of complementary integrative medicine (CIM) to treat their chronic pain symptoms, 60% (n = 45) of participants espoused prior use to treat their chronic LBP symptoms, and of those, 28.9% (n = 13) tried multiple CIM therapeutic modalities. For the full sample, the average length of pain was 62.93 months (SD = 58.62, range from 3 to 336 months) with an average intensity of 4 out of 10 reported on the Numerical Rating Scale, which is clinically indicative of moderate pain.

Table 1. LBP Profile at Baseline

	UC + PEMF** n=39	UC only n=36
Duration of pain		
Mean number of years	6	4
Range	0.4 to 28	0.3 to 15
Pain Intensity Numeric Rating Scale (NRS-11)		
Mean score**	4 (n = 34)	4 (n = 33)
Range**	1- 10	0 - 9
#, % with moderate pain $\geq$ 5**	14, 41%	2, 6%
#, % with severe pain $\geq$ 7**	6, 18%	5, 15%
Pittsburg Quality of Sleep Index (PQSI)		
#, % with pain $\geq$ 3 nights/week	21 (n = 36), 58%	15 (n = 33), 46%
Short Form 12, v.2 (SF-12, v.2)		
#, % with "quite a bit" or "extreme" interference with normal work due to pain	11 (n=36), 30%	10 (n = 33), 30%
Medication History		
#, % participants prescribed opioids	8 (n = 36), 22%	4 (n = 33), 12%

**UC = Usual Care; PEMF = Pulsed Electromagnetic Frequency

At 60%, the rate of CIM among military SMs is higher than prior studies wherein 39-51% of military SMs, depending on service affiliation, reported using a CIM modality within the past 12 months.[6-7] Over the last 5 years, military medicine has increased access to CIM treatment modalities within the military health system (MHS) as the foundation for a new paradigm for maintaining health, treating illness, and improving readiness and performance.[8]   This increase in usage is likely a reflection of increased access to CIM modalities within the MHS.

AIM 1: Efficacy (Primary Outcomes)
(1) Does self-treatment with the Biomodulator when combined with usual care (medication management and LBP education) significantly reduce the intensity of SMs' chronic LBP symptoms, when compared to usual care alone?
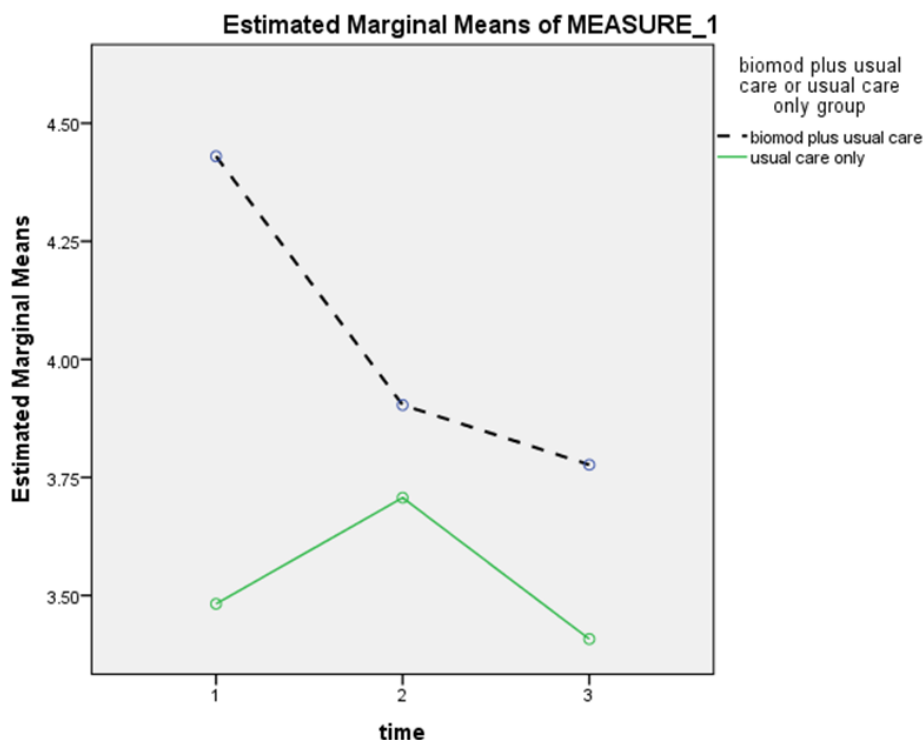
Findings

   To compute an average pain score for each phase, the participant had to have at least 9 of 12 recorded pain scores on their pre-, post-, and 1-month follow-up pain logs. Table 2 provides descriptive statistics for the pain intensity at baseline (NRS_T0), post-treatment (NRS_T4), and one-month follow-up (NRS_T8) for each treatment group.

Table 2. Descriptive Statistics for Pain Intensity across Time

Statistics

cohort_wk0 biomod plus usual care or usual care only group			NRS_T0 Average NRS Score for T0	NRS_T4 Average NRS Score for T4	NRS_T8 Average NRS Score for T8
1.00 biomod plus usual care	N	Valid	36	29	25
		Missing	3	10	14
	Mean		4.3319	3.9023	3.7767
	Std. Error of Mean		.29327	.28802	.46182
	Median		4.1667	3.6667	3.3333
	Mode		2.50[a]	3.33	1.67
	Std. Deviation		1.75962	1.55106	2.30912
	Variance		3.096	2.406	5.332
	Skewness		.633	.161	.384
	Std. Error of Skewness		.393	.434	.464
	Kurtosis		1.012	-.419	-.950
	Std. Error of Kurtosis		.768	.845	.902
	Range		8.33	6.58	8.33
	Minimum		1.33	.67	.17
	Maximum		9.67	7.25	8.50
	Sum		155.95	113.17	94.42
2.00 usual care only	N	Valid	32	30	28
		Missing	4	6	8
	Mean		3.5026	3.7737	3.4077
	Std. Error of Mean		.39978	.37309	.41253
	Median		2.6250	3.2500	3.2083
	Mode		2.25	3.25	3.25
	Std. Deviation		2.26152	2.04351	2.18291
	Variance		5.114	4.176	4.765
	Skewness		.640	.316	.104
	Std. Error of Skewness		.414	.427	.441
	Kurtosis		-.658	-.866	-1.016
	Std. Error of Kurtosis		.809	.833	.858
	Range		7.92	7.50	7.08
	Minimum		.00	.00	.00
	Maximum		7.92	7.50	7.08
	Sum		112.08	113.21	95.42

a. Multiple modes exist. The smallest value is shown

   For the mixed ANOVA, the 2 x 3 (group x phase) interaction was not significant: $F_{(2, 102)} = 1.5$, $p = .228$ ($\eta2 = .029$) nor were the main effects for time ($p = .279$, $\eta2 = .025$) or group ($p = .305$, $\eta2 = .021$). Even though the interaction was not significant, the PEMF + UC group had higher mean pain scores across all three phases compared to usual care.

Graph 1. Estimated Marginal Means across Time for Pain

Relationship of current findings to previous findings:

There was no appreciable statistically or clinically significant reduction in pain scores for SMs who self-administered PEMF in addition to the usual care regimen of LBP education and medication management. Graph 1 demonstrates that although not significant, pain scores trended downward during the active treatment phase and the four-week follow-up phase for participants in the UC + PEMF group. In contrast, pain scores trended upward for the UC only group during the first four-weeks with a steady decline during the one month follow up period. This is not reflective of a 2016 randomized controlled study by Lee and colleagues in which PEMF produced significant LBP symptom reduction from baseline to follow-up when compared to placebo.[9]

There are several potential reasons for these findings. First, there were significant differences between groups in mean pain scores at baseline even though participants were randomly allocated to treatment groups. Additionally, the influence of treatment bias for participants enrolled in the PEMF + UC group cannot be overlooked; unlike the UC only group, these participants received a device to add to their treatment regimen. Kaptchuk and colleagues argued that participants receiving procedures or treatments in addition to usual care can experience heightened expectations; and in fact, the procedures, which the authors considered to be an estimate of the magnitude of the placebo effect under conditions of heightened expectations, can bias the results.[10] Future studies in military samples should employ a sham device in an effort to negate these heightened expectations. Finally, there may have been quantitative between-group differences in participants' level of weekly stretching and strengthening, continued medication use, or device usage that was not accurately captured in the self-report treatment and medication logs. A follow-on study using a larger sample size with

witnessed treatment administration is the next logical step to control for these potential confounders.

(2) Does self-treatment with the Biomodulator when combined with usual care (medication management and LBP education) significantly reduce SMs consumption of oral analgesic medications to treat their chronic LBP symptoms, when compared to usual care alone?

Findings

 Participants recorded the amount of opioid and non-opioid analgesic medications consumed over a four- day period at baseline, post-treatment, and one-month follow up on a Pain Medication & Exercise Diary. The amount of pain medication consumed was then quantified using the Medication Quantification Scale Version III.[11] The hypothesis was that there would be a significant reduction in the amount of analgesic medications consumed by participants receiving PEMF + UC when compared to those receiving UC only.

 One challenge with analyzing this research question was the plethora of 0's (> 80% were "0" for analgesic consumption) in the data. With this severe skewness, transformations such as log or inverse are rarely effective in normalizing the distribution. Therefore, a generalized estimating equation (GEE) analysis was also calculated to confirm the results of the Mixed ANOVA. A GEE is often done to accommodate the non-normal/exponential distributions, such as what occurred in this study.[12]

 Though not significant, overall the PEMF + UC had a higher mean oral analgesic consumption rate (M = 23.82) vs the UC group (M = 8.62) at baseline—with an incline throughout the active treatment phase and then a decrease at the last wave of measurement from post-treatment to one-month follow-up. For the UC only group, there was an increase from week 4 to week 8 of study participation.

Table 3. Medication Use by Group over Time

	Baseline T0	Post-Treatment T: 4 Weeks	Follow-up T: 8 Weeks
Percent Endorsing No Medication Use			
UC + PEMF	78% (n = 28)	80% (n = 23)	85% (n = 22)
UC only	88% (n = 28)	90% (n = 27)	89% (n = 25)
Average Pain Medication Use: M (SD)			
UC + PEMF	24.4 (52.3)	28.0 (68.4)	21.5 (58.5)
UC only	8.3 (26.0)	8.3 (31.3)	9.3 (35.5)

**UC = Usual Care; PEMF = Pulsed Electromagnetic Frequency; T = Time; M = Mean; SD = standard deviation

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Graph 2. Average Medication Dose Equivalents per Group over Time
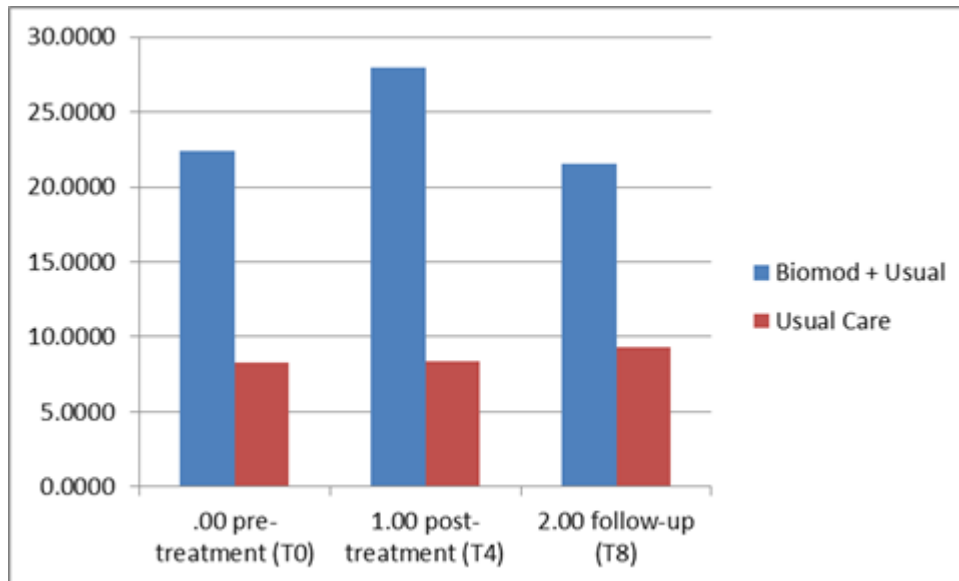
The results of the mixed ANOVA showed that the group x time interaction was not significant (as shown in Table 3). Graph 3 shows the trends in the data across time for medication consumption.

Table 4. 2 x 3 Mixed ANOVA of Medication Consumption

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
time	Sphericity Assumed	558.364	2	279.182	1.077	.344	.021
	Greenhouse-Geisser	558.364	1.212	460.885	1.077	.317	.021
	Huynh-Feldt	558.364	1.249	446.877	1.077	.319	.021
	Lower-bound	558.364	1.000	558.364	1.077	.304	.021
time * cohort_wk0	Sphericity Assumed	75.345	2	37.673	.145	.865	.003
	Greenhouse-Geisser	75.345	1.212	62.192	.145	.753	.003
	Huynh-Feldt	75.345	1.249	60.301	.145	.760	.003
	Lower-bound	75.345	1.000	75.345	.145	.705	.003
Error(time)	Sphericity Assumed	26437.548	102	259.192			
	Greenhouse-Geisser	26437.548	61.787	427.884			
	Huynh-Feldt	26437.548	63.723	414.879			
	Lower-bound	26437.548	51.000	518.383			

Graph 3. Estimated Marginal Means across Time for Medication Consumption
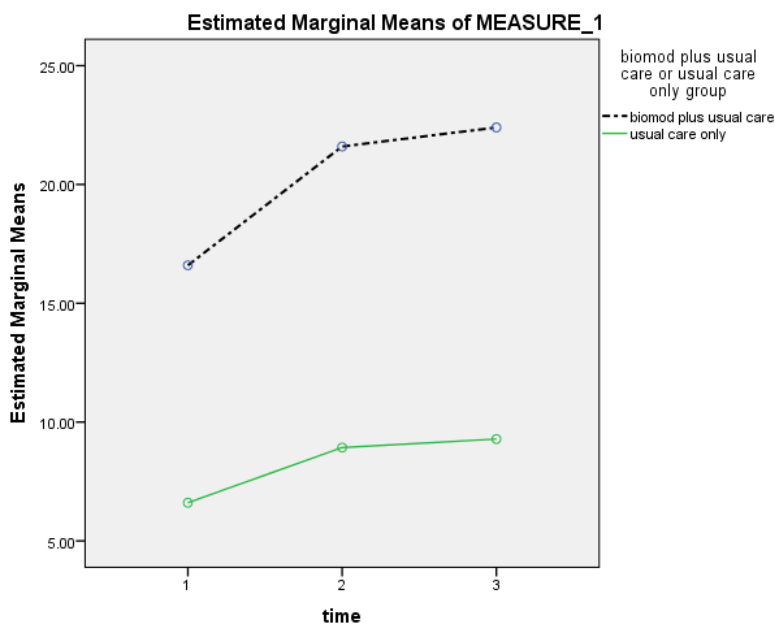
The GEE with negative binomial distribution and log link function (though usually used for count data) was able to accommodate the actual "0" values. When using the negative binomial distribution with log link function for the GEE analysis, as with the gamma distribution, the time x cohort interaction was not significant: Wald $\chi2$ (2) = .984, p = .612 nor were the individual predictors (i.e., group or time).

Table 5. Model Effects for GEE Analysis

Tests of Model Effects

Source	Type III		
	Wald Chi-Square	df	Sig.
(Intercept)	52.688	1	.000
cohort_wk0	1.920	1	.166
Time	.372	2	.830
cohort_wk0 * Time	.984	2	.612

Dependent Variable: Morphine Equivalent Dose via the online Opioid Dose Calculator v1.9
Model: (Intercept), cohort_wk0, Time, cohort_wk0 * Time

Relationship of current findings to previous findings:
  Two interesting findings emerged in the analysis of SMs' reported medication use for treatment of their chronic pain symptoms on the four-day medication logs collected at baseline, post-treatment, and 1-month follow-up. First, many SMs in this study did not routinely rely on medications to treat their chronic LBP symptoms as demonstrated by the fact that 82% (n = 56)

of SMs in the sample reported no medication use at baseline; 85% (n = 50) reported no medication use at 4 weeks; and 87% (n = 47) reported no medication use at 8 weeks. A 2014 Veterans Health Administration study of prescription medication use in SMs found that approximately 50% of patients with chronic noncancer pain were prescribed opioids and participants' median daily consumption of analgesic medications was 21mg morphine dose equivalents.[13] Findings from this study show that, at baseline, only 28% of participants were prescribed opioids for treatment of their chronic pain symptoms, and their median daily consumption was 0 mg morphine equivalents (N = 68; M = 15.8, SD = 42.3). The higher rate of CIM use, the lower rate of opioid prescriptions, and the lower daily analgesic consumption in this sample appears to be consistent with the recommendations of the 2007 US VA/DoD Evidence-Based Practice clinical practice guideline for the diagnosis and treatment of low back pain.[14] The guideline specifically recommends chronic LBP sufferers use nonpharmacological treatments, in conjunction with non-opioid first line analgesic medications like acetaminophen or NSAIDs, and to avoid opioid analgesic prescribing except in intractable pain. Table 3 also provides the between group differences in pain medication consumption at baseline, after active treatment, and at follow-up for both groups. Second, although the percentage of SMs using medications to treat their pain slightly decreased during active treatment with PEMF + UC, the average amount of medications taken by SMs in this group actually trended upwards. No studies of adjunctive PEMF in chronic pain management have been found that examine medication use as an outcome variable of interest. This trend is not consistent with findings from a study of post-operative pain management with PEMF in women with breast surgery, which showed a threefold decrease in the amount of pain medications consumed by those in the active versus and sham group by post-op day (p <0.001).[15] Perhaps these findings can be explained by differences in the unique nature of acute versus chronic pain or the fact that chronic LBP can be activity dependent, necessitating treatment with adjunctive medications intermittently.

AIM 2: Variability (Secondary Outcomes)
(3) Does adjunctive self-treatment of chronic LBP symptoms with the Biomodulator produce variability in the bio-psycho-social secondary sequelae of chronic LBP (depression, anxiety, and post-traumatic stress symptom severity, sleep quality, LBP-related disability, self-reported mental and physical HrQoL, social support and social conflict) in SMs, when compared to usual care alone?

Findings
At baseline, post-treatment, and one-month follow-up, participants completed a battery of instruments to measure the biopsychosocial sequelae often associated with chronic LBP. These instruments included: The Post-Traumatic Stress Disorder Checklist-Military Version (PCL-M); PRIME-MD® Patient Health Questionnaire Mood module (PHQ-9) and Anxiety module (GAD-7); Pittsburgh Sleep Quality Index (PSQI); Oswestry Low Back Pain Disability Questionnaire (ODQ); Short Form-12 version 2 (SF-12, v2) comprised of a Mental Component Summary Score (MCS) and Physical Component Summary Score (PCS); and The Interpersonal Relationships Inventory-Short Form (IPRI-SF) consisting of a social support and social conflict subscale. Table 6 provides the means and standard deviations to examine variability in the phenomena over time, as well as the 2 X 3 ANOVA F statistic to examine whether significant group differences over time existed. Secondary analyses of significant findings were performed using multilevel modeling (MLM).

Table 6. Variability in Secondary Outcomes (Biopsychosocial Sequelae of Chronic LBP)

Variable *Group*	Time 1: Baseline Pre-Treatment		Time 2: 4 Weeks Post-Treatment		Time 3: 8 Weeks 1 month F/U		2 x 3 (group x time) Mixed ANOVA interaction		
	M	SD	M	SD	M	SD	*F*	*p*	*η2*
Depression									
UC + PEMF	5.2	5.0	4.6	5.0	4.6	5.6	*F* (2, 104) = 1.56	.219	.029
UC only	4.9	4.8	3.6	3.5	3.7	3.3			
Anxiety									
UC + PEMF	3.9	4.6	3.8	4.9	4.5	6.0	*F* (2, 104) = 5.28	**.007**	.092
UC only	4.3	4.7	2.4	2.6	2.6	3.4			
PTSD									
UC + PEMF	29.5	15.4	27.0	14.2	28.0	15.9	*F* (2, 104) = .515	.599	.01
UC only	45.4	8.4	44.8	7.3	46.4	7.9			
Sleep Quality									
UC + PEMF	8.2	4.3	7.4	4.7	7.6	4.9	*F* (2, 102) = .011	.989	<.001
UC only	8.6	3.9	8.5	4.0	8.0	4.1			
LBP Disability									
UC + PEMF	39.8	14.8	34.6	17.5	35.8	21.4	*F*(2, 104) = 28.62	.506	.11
UC only	34.9	15.3	33.9	15.2	33.3	15.6			
Mental HrQoL									
UC + PEMF	54.8	5.8	54.0	8.9	53.8	9.8	*F*(2, 104) = 4.02	**.018**	.075
UC only	51.8	8.6	54.4	9.0	53.8	7.5			
Physical HrQoL									
UC + PEMF	42.8	9.9	45.5	10.3	43.5	11.6	*F*(2,104) = 4.20	**.018**	.075
UC only	45.4	8.4	44.8	7.3	46.4	7.9			
Social Support									
UC + PEMF	57.9	6.4	60.2	4.8	57.0	10.2	*F*(2, 104) = 1.92	.164	.036
UC only	57.2	6.4	55.6	7.3	55.8	7.1			
Social Conflict									
UC + PEMF	31.1	8.1	29.5	7.7	32.4	11.3	*F*(2, 104) = 2.25	.111	.041
UC only	31.0	8.7	30.3	9.8	30.1	9.0			

**F/U = Follow-up; UC = Usual Care; PEMF = Pulsed Electromagnetic Frequency; F/U = Follow Up;
M = Mean; SD = Standard Deviation; PTSD = Post traumatic Stress Disorder; HrQoL = Health-related Quality of Life

Depression and PTSD symptom severity, LBP-related disability, social support, social conflict, and sleep quality demonstrated statistically non-significant variability and between group differences over time in the usual care and usual care plus PEMF groups. Unexpectedly, anxiety symptom severity decreased in the UC group from an average of 4.3 (SD = 4.7) at baseline to 2.6 (SD = 3.4) at 1-month follow-up yet increased in the UC + PEMF group from 3.9 (SD = 4.6) at baseline to 4.5 (SD = 6.0) at 1-month follow-up. When examining the estimated means, the usual care group had a higher mean at baseline when compared to the PEMF plus

usual care group, but the pattern was reversed for the subsequent two time periods (i.e., higher means obtained for PEMF + UC group, see Graph 4). For the mixed ANOVA, the 2 x 3 (group x time) interaction was significant: $F(2, 104) = 5.28$, $p = .007$ ($\eta2 = .092$); however, the main effects for time ($p = .271$, $\eta2 = .025$) or group ($p = .372$, $\eta2 = .015$) were not significant as is expected in repeated measures designs.

**Graph 4. Estimated Marginal Means for Anxiety Symptom Severity Scores**
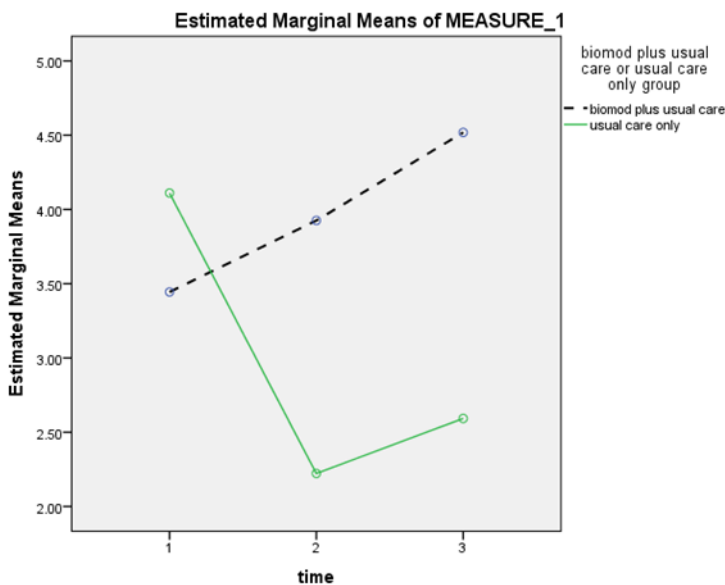
The MLM secondary analysis showed that the cross-level interaction of group x time remained significant for the anxiety outcome variable: $F(2, 110.68) = 4.78$, $p = .01$. Overall, neither of the individual predictors were significant, i.e., for group: $F(1, 64.97) = .1.09$, $p = .301$ nor time: $F(2, 110.68) = 1.99$, $p = .142$. However, when examining the individual partial coefficients, significance is obtained for the coded vector for Week 1 (Baseline) when compared to Week 9 (1 month follow-up): $b = -2.42$, $p = .013$. Moreover, the group x time interaction term yielded a significant coefficient when comparing Baseline to 1-month follow-up data: $b = -.27$, $p = .006$. [Note: when time is modeled as a continuous variable, the interaction was still significant: $b = 1.23$, $p = .005$]. The conditional intraclass correlation coefficient (ICC) = .748, indicating that 74.8% of the variability was accounted for by differences in the individual intercepts. Given the non-normality of the outcomes, a log (base 10) transformation was performed on each of the anxiety dependent variables, and the group x time interaction was still significant ($p = .015$).

The SF-12, v.2 Physical Health Component Scores (PCS) demonstrated significant between group differences over time. When examining the estimated means, the usual care group had a higher mean at baseline and 1-month follow-up when compared to the usual care + PEMF group, but the pattern was reversed for post-treatment PCS scores, where a higher mean was obtained for usual care + PEMF group (See Graph 5). The mixed ANOVA 2 x 3 (group x time) interaction was significant for the PCS: $F(2, 104) = 4.75$, $p = .011$ ($\eta^2 = .084$) and neither of the main effects were significant for time ($p = .237$, $\eta^2 = .027$) and group ($p = .445$, $\eta^2 = .011$). There was also a significant interaction for the quadratic term: $F(1, 52) = 10.23$, $p = .002$ ($\eta^2 =$

.164). The usual care group had a higher mean at baseline and 1-month follow-up when compared to the usual care + PEMF group; however, the pattern was reversed insofar as a higher mean was obtained for usual care + PEMF group at post-treatment. When examining the simple effects analysis, there were no between-group differences at any of the specific waves of data collection

Secondary analysis using MLM confirmed the cross-level interaction of group x time was significant for the PCS: $F (2, 112.62) = 3.76$, $p = .026$. Overall, neither of the individual predictors were significant, i.e., for group: $F (1, 67.11) = .223$, $p = .638$ nor for time: $F (2, 112) = 1.37$, $p = .259$. Moreover, the group x time interaction term yielded a significant coefficient when comparing post-treatment to 1-month follow-up: $b = 3.65$, $p = .034$. [Note: when time is modeled as a continuous variable, the interaction is not significant: $b = .35$, $p = .692$]. The conditional intraclass correlation coefficient (ICC) = .762, indicating that 76.2% of the variability was accounted for by differences in the individual intercepts.

**Graph 5. Estimated Marginal Means for Physical Health Component Scores**
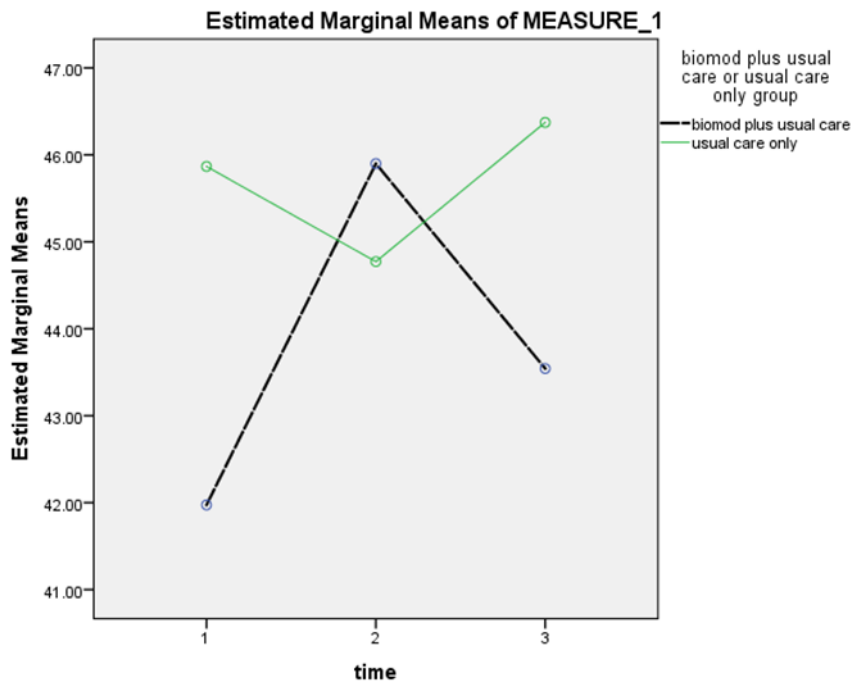
The SF-12, v.2 Mental Health Component Scores (MCS) demonstrated significant between group differences over time as well. The usual care group has a higher mean at baseline when compared to the usual care + PEMF group, but the pattern was reversed for the next two waves of data collection, with the usual care only group having higher means than the usual care + PEMF group (See Graph 6). When examining the simple effects analysis, there is a significant between group difference at Baseline: $F (1, 52) = 4.70$, $p = .035$ ($\eta2 = .083$).

For the mixed ANOVA (keeping in mind the smaller sample size, n = 54), the results of the 2 x 3 (group x time) interaction were significant: $F (2, 104) = 4.20$, $p = .018$ ($\eta2 = .075$) and neither of the main effects were significant for time ($p = .599$, $\eta2 = .01$) nor group ($p = .605$, $\eta2 = .005$). For the MLM secondary analysis, the cross-level interaction of group x time was

significant for the SF 12 MCS: $F (2, 112.5) = 3.26$, $p = .042$. Overall, neither of the individual predictors were significant, i.e., for group: $F (1, 65.71) = .074$, $p = .786$ nor time: $F (2, 112.5) = .233$, $p = .783$. Moreover, neither of the group x time interaction terms yielded a significant coefficient, though when comparing Week1 to Week9: b = 3.55, $p = .051$. [Note: when time is modeled as a continuous variable, the interaction is still significant: b = -1.84, $p = .043$]. The conditional intraclass correlation coefficient (ICC) = .665, indicating that 66.5% of the variability was accounted for by differences in the individual intercepts. Given the non-normality of the outcomes (i.e. negative skewness), a log (base 10) transformation was performed on each of the MCS dependent variables and the group x time interaction was significant (p = .013) as well as the effect for time (p = .018).

Graph 6. Estimated Marginal Means for Mental Health Component Scores
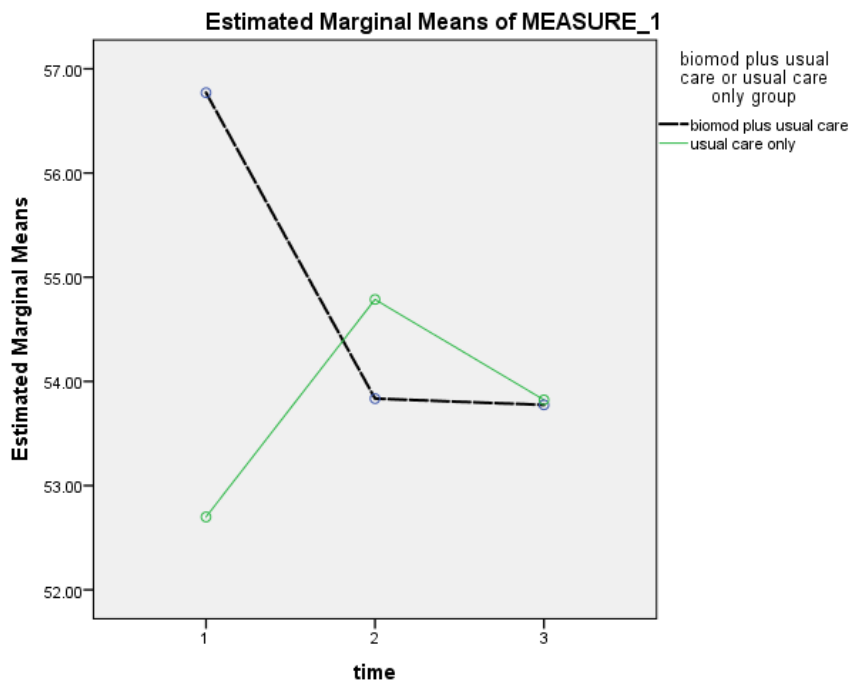
Relationship of current findings to previous findings:

   Comorbid mental health conditions have been well-established correlates of chronic pain conditions.[16-19] Borrowing from the Biopsychosocial Model of Chronic Pain, patients with a history of chronic depression, PTSD, and anxiety have a psychological vulnerability to developing chronic pain syndromes.[20] In addition, this affective vulnerability can increase the intensity of a person's response to pain or disability.[21] Given the 14 years of sustained war and multiple deployments, rates of depression, anxiety, and PTSD have increased dramatically among SMs, as have chronic pain conditions. [16-19]   Therefore, it was surprising in this sample of SMs that the baseline mean scores for these co-morbid conditions were so low. Cut-off scores for mild symptoms on the GAD7 for measuring anxiety symptom severity, the PHQ-9 for measuring depression symptom severity, and the PCL-M for measuring PTSD symptom severity are 5, 10, and 50, respectively.[22-23] That being said, baseline mean scores for the full sample in this study were 4.1 (SD = 4.6) for anxiety; 5.0 (SD = 4.9) for depression; and 29.3 (SD = 13.5) for PTSD. Overall mean scores in both treatment groups decreased on average by no more than

2.5 points on these scales, representing a clinically and statistically nonsignificant outcome effect.

　　Regarding between group comparisons of anxiety severity scores, there were appreciable differences in participants receiving usual care + PEMF when compared to usual care alone. The usual care group experienced an appreciable decrease in anxiety symptoms during the first 4-week period with a slight increase during the last 4-week period, while the usual care + PEMF group experienced a small but steady increase in anxiety symptoms over the full 9 weeks of study participation. The literature on electroanalgesia in general, or the Biomodulator device specifically, doesn't mention anxiety as a potential side effect of treatment;[5, 24-25] however, no studies of PEMF were found that specifically examined anxiety as an outcome variable. While self-treatment with a new device in and of itself could raise the anxiety symptoms in this group, one would not expect to see a sustained increase during the four-weeks after active treatment when the PEMF treatment was stopped.　Additionally, it was the greater drop in anxiety symptom severity in the usual care group over the small increase in anxiety symptoms in the usual care + PEMF group that was more responsible for the significant between group differences.

　　The concept of health-related quality of life and its determinants has evolved since the 1980s to encompass aspects of overall quality of life that clearly impact health outcomes, both physical and mental.[26]　At the individual level, patient self-reports of HrQoL have become important measures to assess treatment effectiveness, especially for patients with chronic LBP, as the complete absence of pain may not be an attainable treatment goal.　Findings from this study indicate that adjunctive PEMF in addition to usual care improved self-reported physical HrQOL and led to diminished mental HrQOL in SM's with chronic LBP symptoms when compared to those treated with usual care only.　Baseline HrQoL measurements of 77,047 US service members participating in The Millennium Cohort study found unadjusted mean PCS and MCS scores of 53.4 (95% confidence interval: 53.3–53.4) and 52.8 (95% confidence interval: 52.7–52.9), respectively; although this baseline data was collected in 2001-2003 prior to the start of Operations Iraqi Freedom and New Dawn.[27] SMs with chronic LBP in this study had a baseline mean PCS of 44.0 (SD = 8.8) and MCS of 53.4 (SD = 7.3). Physical component scores were slightly less favorable in this military sample compared to those of the US general population of the same age and sex and mental component scores were slightly more favorable. In contrast, studies of both Canadian military veterans and Persian Gulf veterans found that chronic physical health conditions such as chronic pain and musculoskeletal conditions were associated with poorer PCS scores and poorer MCS scores.[28-29]

　　Unexpectedly, findings from this study indicate that adjunctive PEMF in addition to usual care diminished self-reported mental HrQoL.　In support of this finding, there was a mild but sustained increase in anxiety symptoms throughout the course of treatment for the usual care + PEMF participants that cannot be fully explained; and it is in contrast to small, clinically insignificant decreases in reported depression and PTSD symptom severity in this group.

AIM 3: Feasibility (Research Design)
(4) What are the participant retention rates, refusal rates, treatment failure/success rates, and adherence/non-compliance rates for study participants in both intervention arms?

Retention and Withdrawal Findings:
A targeted sample size of 35 subjects per treatment group (N= 70) was projected. Oversampling to a maximum of 75 participants occurred to account for participant attrition. There were 229 potential participants contacted, 84 screened for study participation and of those, 9 were ineligible for study participation based on inclusion/exclusion criteria. Seventy-five patients consented for study participation; 39 were randomly assigned to receive usual care + PEMF and 36 to receive usual care only. Ten participants withdrew from the usual care + PEMF group and eight from the usual care only group producing a 24% overall attrition rate, and a 2.7% differential attrition rate.

Reasons participants gave for not completing the study are as follows:
- Six participants were lost to follow-up. Multiple attempts at contact were made via email and telephone without success.
- Nine participants dropped out from the study for the following reasons: initiation of a medical board (n = 1); conflict with military duties (n = 5); attempting to get pregnant (n = 1); became pain free after enrolling and did not wish to continue (n = 1); no reason provided (n = 1).
- Three participants had to be withdrawn from the study because of their decision to pursue alternate interventions to alleviate their pain: steroid injections (n = 1) and surgery (n = 2).

Treatment Failure/Success and Adherence Findings:
Twenty-four out of thirty participants receiving usual care + PEMF reported their treatment as a "partial" (n = 21) or "complete (n = 3) success" while 26 (87%) out of 30 participants receiving the usual care intervention reported their treatment a "partial success" and none reported it a "complete success." With regard to the item "did you find it easy or difficult to adhere to the treatment plan" 39.7% (n = 23) of participants endorsed the "Very Easy" option and 39.7% (n = 23) endorsed the "Somewhat Easy" option. When comparing the two groups, 44.8% (n = 13) endorsed the "Somewhat Easy" option for the usual care only group compared to 41.4% (n = 12) that endorsed the "Very Easy" option in the usual care + PEMF group. No participants from either group reported difficulty adhering to their prescribed treatment plan. When it came to adherence with survey completion, 100% of participants (n = 75) completed the Health and Social History and Demographic Data Sheet at the time of consent, 91.9% (n = 68) completed all other study-related instruments at baseline, 82.4% (n = 61) at the post-treatment, and 77% (n = 57) at 1-month follow-up. Table 7 outlines participants' perception of their treatment as a success or failure and their perception of how easy it was to adhere to the treatment plan.

Table 7. Participant attitudes toward treatment failure/success and adherence

	Usual Care + PEMF n=30	Usual Care Only n=30
	Frequency (%)	Frequency (%)
Did you feel this treatment intervention was a success or failure?		
Complete Success	3 (10)	0 (0)
Partial Success	21 (70)	26 (87)
Partial Failure	5 (17)	4 (13)
Complete Failure	1 (3)	0 (0)
Did you find it easy or difficult to adhere to the treatment plan?		
Very Easy	15 (50)	11 (37)
Somewhat Easy	9 (30)	14 (47)
Somewhat Difficult	6 (20)	5 (17)
Very Difficult	0 (0)	0 (0)

(5) *Do subjects provide no answer, multiple answers, qualified answers, or unanticipated answers to study questions?*

An analysis of participant responses on completed study surveys during data entry and analysis and of the study log book demonstrated no pattern to missing data, no qualified (double or conflicting responses), and no unanticipated answers to study questions. During the course of the study, one participant endorsed suicidal ideations on the PHQ-9 Depression symptom inventory and safety procedures for the study were implemented per protocol without incident. There were no side effects reported by participants enrolled in the PEMF study group. Table 8 provides the reliability estimates for the study instruments in this study as well as those reported in the literature from the original study manuscript.

Table 8. Instrument Reliability

Instrument	Cronbach's Alpha Range for this Study	Cronbach's Alpha reported in literature
PHQ-9	.857 - .865	.86 - .89 [30]
GAD-7	.890 - .942	.92 [31]
PCL-M	.954 - .963	> .90 [32]
IPRI-SF Social Support	.892 - .961	.92 [33]
IPRI-SF Social Conflict	.877 - .928	.91 [33]
ODQ	.865 - .914	.71 to .87 [34]
PSQI	.756 - .811	.83 [35]
AARP	.884	.95-.98 [36]

(6) How long does it take study participants to complete the study forms?

In response to the question, "On average, how much time did it take you each week to complete the study treatments and medication logs?" participants in the usual care + PEMF group reported it took them an average of 3.49 hours (SD = 6.94, Median = 1.5). Participants in the usual care group reported it took them an average of 2.03 (SD = 3.77, Median = 1.0) hours to complete the study logs and treatments.

(7) What is the overall acceptability of the interventions by study participants?

At post-treatment, participants completed the 8-item Abbreviated Acceptability Rating Profile. The 8 items are on a six point Likert-type scale ranging from 1 = "strongly disagree" to 6 = "strongly agree." Higher scores are indicative of greater treatment acceptability. Table 9 provides the description of the question and descriptive statistics for each group.

Acceptability Findings
   For the full sample, the average AARP score was 37.08 (SD = 7.16, range from 14 to 48) with a coefficient alpha of .886. When comparing the groups, a higher mean was obtained for the Usual Care + PEMF group (M = 38.69, SD = 7.91) compared to the Usual Care only group (M = 35.53, SD = 6.08). For the one-way ANOVA between group mean differences were not significant: $F (1, 57) = 2.97$, $p = .09$ ($\eta2 = .049$).

Table 9. Acceptability of Interventions (Usual Care + PEMF vs. Usual Care only)

Descriptive Statistics

cohort_wk0 biomod plus usual care or usual care only group		N	Minimum	Maximum	Mean	Std. Deviation
1.00 biomod plus usual care	AARP_wk5_1 This is an acceptable intervention for treating chronic low back pain symptoms	29	1.00	6.00	4.2414	1.37983
	AARP_wk5_2 I am willing to use this treatment again for treating my chronic low back pain symptoms	29	1.00	6.00	4.5172	1.47892
	AARP_wk5_3 There are no bad side effects for people using this intervention to treat their chronic low back pain symptoms.	29	1.00	6.00	5.0000	1.46385
	AARP_wk5_4 I liked this treatment	29	1.00	6.00	4.5862	1.35006
	AARP_wk5_5 Overall, the intervention was easy to self-administer	29	4.00	6.00	5.6897	.54139
	AARP_wk5_6 Overall, the time spent performing the intervention was reasonable	29	2.00	6.00	5.5862	.86674
	AARP_wk5_7 Overall, this intervention is beneficial for treating chronic low back pain	29	1.00	6.00	4.3448	1.58736
	AARP_wk5_8 I would recommend this intervention to friends and family who have chronic low	29	1.00	6.00	4.7241	1.53289
	Valid N (listwise)	29				
2.00 usual care only	AARP_wk5_1 This is an acceptable intervention for treating chronic low back pain symptoms	30	2.00	5.00	4.2333	.81720
	AARP_wk5_2 I am willing to use this treatment again for treating my chronic low back pain symptoms	30	2.00	6.00	4.4333	.85836
	AARP_wk5_3 There are no bad side effects for people using this intervention to treat their chronic low back pain symptoms.	30	2.00	6.00	4.6667	1.18419
	AARP_wk5_4 I liked this treatment	30	1.00	5.00	4.0667	1.08066
	AARP_wk5_5 Overall, the intervention was easy to self-administer	30	2.00	6.00	4.6667	1.12444
	AARP_wk5_6 Overall, the time spent performing the intervention was reasonable	30	2.00	6.00	4.8667	.86037
	AARP_wk5_7 Overall, this intervention is beneficial for treating chronic low back pain	30	2.00	6.00	4.3000	1.08755
	AARP_wk5_8 I would recommend this intervention to friends and family who have chronic low	30	1.00	6.00	4.3000	1.14921
	Valid N (listwise)	30				

Discussion Aim 3

Attrition, a universal phenomenon in longitudinal research, is the loss of randomly assigned participants or participants' data, which can bias a randomized controlled trial's external validity by producing a final sample that is not representative of the population sampled.[37] Differential attrition rates of <5 % are not considered concerning for introducing bias into study results; therefore, attrition for this study was minimal. Frequent contact with study participants and a willingness to be flexible with appointment times for follow-up visits were essential to minimal attrition of study participants. Military commitments were a factor for some participants who withdrew from study participation. Future studies need to minimize study burden as much as possible. Fortunately, attrition from both treatment groups in this study was similar for a variety of reasons previously outlined.

The majority of service members from both groups believed that Usual Care + PEMF and Usual Care only for treatment of their LBP symptoms were at least partially successful and reported relative ease with adhering to the treatment regimen to which they were assigned. No prior studies were found that examined participants' attitudes towards PEMF self-treatment or the difficulty with self-administering the treatment. These findings are suggestive that SMs may be amenable to adjunctive self-treatment with PEMF for their chronic back pain but recognize the importance of traditional medical management.

Reliability estimates for the instruments used in this study performed as expected with the exception of the Abbreviated Acceptability Rating Profile. (See Table 8). This instrument was changed from its original version to reflect chronic LBP specific language. Examination of the individual items found that on average SMs rated both interventions favorably.

Limitations

Limitations in this study include a small sample size recruited from a single military treatment facility. As a pilot study, its intent was to determine whether PEMF effectively reduced pain and medication use in SMs with chronic LBP. Although participants were randomized to treatment group, the usual care + PEMF group had higher mean pain scores and pain medication consumption at baseline than the usual care only group. It is unknown whether the treatment effect with PEMF may have been more appreciable in this group because of their higher baseline pain scores, or whether their increased use of pain medications at baseline was the consequence of more intractable pain symptoms, hence affecting their response on instruments measuring these and other outcomes. Additionally, the use of usual care as a pragmatic comparator in this study introduced several confounders that could not be completely accounted for; namely, validation of participant PEMF self-treatment compliance, the accuracy of medication accounting, and overall, a baseline recognition of how little SMs used medications to treat their chronic LBP symptoms.

A larger full-scale multi-site study is necessary to verify the effectiveness of PEMF when compared to sham treatment to provide greater validation of the study findings. Since the start of this study and the release of the Army Pain Task Force 2010 Report, the military medical community has provided increased pain management education to its healthcare providers, made complementary integrative medicine modalities more accessible to its beneficiaries, and enacted greater restrictions and better monitoring of opioid prescribing patterns and polypharmacy. It is unknown whether this new reality in pain treatment may have had untoward effects on medication use in this sample. Possibly, SMs' lack of reliance on medications to treat chronic LBP symptoms could also signal their willingness to use complementary integrative medicine

modalities like electroanalgesia in lieu of medications to treat their symptoms. Further examination of increased anxiety as a potential side effect is also warranted. Because of the greater vulnerability for increased mental health issues in SMs due to ongoing deployments and combat exposure, it is critical that the medical community not introduce new therapies that could have detrimental side effects without proper baseline screening.

Conclusion:

In the U.S. Armed Forces, chronic LBP is among the most frequent complaints for medical visits, lost work time, and attrition from active duty and the deployed setting. Although analgesics and LBP education have been effective for treating acute LBP, these treatments have not been equally effective for treating chronic LBP symptoms. In addition, over-prescribing of analgesic medications by military healthcare providers to manage chronic pain has led to an increase in reported cases of SM opioid abuse, overdose due to poly-pharmacy, and untoward side effects. The findings from this randomized-controlled, pilot study showed that the addition of PEMF to a usual care treatment plan proved no more efficacious than usual care by itself. While there were trends that showed improvement in pain scores for both groups, the results lacked clinical and statistical significance to recommend PEMF as an adjunctive treatment for chronic LBP symptoms. The study also highlighted that SMs infrequently rely on medication management to treat their chronic LBP symptoms.

Secondarily, this study sought to determine whether adjunctive self-treatment PEMF had any effect on the biopsychosocial secondary sequelae of chronic pain, namely, depression, anxiety, post-traumatic stress, sleep quality, LBP-related disability, mental and physical HrQOL, social support and social conflict when compared to usual care. These findings were more interesting in that between group differences did emerge in both mental and physical HrQoL and anxiety symptoms. It was also noteworthy that depression, anxiety, and PTSD scores were low in this group of military SMs with chronic pain symptoms despite the fact these are common co-morbidities in the literature. As more and more research into chronic pain syndromes indicates, the absence of pain cannot be the sole outcome of interest because it is often an unattainable and unrealistic goal. Many population-based studies have focused on HrQoL as a key indicator in intervention studies. Treatment with adjunctive PEMF led to mild increases in anxiety symptoms but significantly poorer mental health related quality of life than in those who received usual care only. Further examination is necessary to validate whether anxiety symptoms could be a previously unknown side effect of PEMF treatment or whether these findings were merely an anomaly that surfaced in this sample of military SMs.

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Significance of Study or Project Results to Military Nursing

For the Military Health System (MHS), chronic musculoskeletal LBP is a particularly salient public health problem in an otherwise young, healthy military population. It is among the most frequent complaints for medical visits, lost work time, and attrition from garrison duty and the combat theater. It not only degrades the health, fitness, and morale of the individual service member (SM), it places considerable burden on the health care system and impacts military operational effectiveness by contributing to the number of SMs discharged from the Armed Services due to physical disability. Although analgesics and LBP education have been effective for treating acute LBP, they have not been equally effective for treating chronic LBP symptoms, leading to an over-reliance on prescription opioids for treatment. In 2011, there was a call to action by the Army Pain Task Force to explore Complementary Integrative Medicine (CIM) treatments that could potentially offer an alternative treatment to medications for those suffering chronic pain symptoms. Pulsed Electromagnetic Field Therapy (PEMF), a CIM modality unexplored in a military population, previously demonstrated efficacy in small scale studies examining muscle recovery and function in injured athletes, pain control, and treatment of musculoskeletal pain and dysfunction. This preliminary pilot study examined the efficacy of adjunctive PEMF in treating musculoskeletal LBP in military SMs and found trends in symptom improvement, although not clinically or statistically significant. This study also uncovered that this sample of military chronic LBP suffers did not rely on regular medication consumption to treat their LBP symptoms.

This pilot study also showed that the addition of PEMF to a usual care LBP treatment regimen significantly improved physical health related quality of life in this military sample. In addition, it found that adjunctive PEMF treatment negatively impacted SMs reported mental health related quality of life and anxiety symptom severity when compared to usual care with medication management and stretching and strengthening exercises. This finding has not been previously reported in the literature and could impact who may or may not benefit from treatment with PEMF. This study informed military-relevant scientific knowledge on the use of PEMF as an adjunctive treatment for SMs with chronic LBP symptoms. It provided preliminary evidence to nurse practitioners and other health care providers that there is not sufficient evidence to recommend prescribing adjunctive PEMF treatment for chronic LBP symptom in military SMs.

It also provided preliminary evidence to policy makers that there is insufficient evidence to support investment in this treatment without further research into its effectiveness. Because this was a small pilot study using usual care as a comparator, it is recommended that a larger randomized controlled sham clinical trial be supported to definitively examine the effectiveness of PEMF for chronic LBP in military SMs. The results of this pilot study, although statistically and clinically not significant, were promising. Due to methodological issues and an inability to control for all confounders in this convenience sample recruited from a single military treatment facility, the results should only be viewed in light of these study limitations.

Furthermore, the proposed study has relevance to military nursing clinical practice. With the tremendous physical, emotional, and spiritual toll that 14 years of war has taken on our military SMs, the widespread reports of chronic pain among SMs, and the overreliance of military health care providers prescribing opioids to treat chronic pain, the military nursing community has been at the forefront of exploring complementary integrative pain treatment modalities. Military nurse

scientists, advanced practice nurses and clinical nurses continually strive to expand the boundaries of the traditional medical model of pain treatment and are the vanguard of advancing the science of holistic, patient-centered, clinical pain management nursing practice. Philosophically, nursing has always been at the forefront of treating patients from a holistic perspective.

Changes in Clinical Practice, Leadership, Management, Education, Policy, and/or Military Doctrine that Resulted from Study or Project

There have been no changes to Clinical Practice, Leadership, Management, Education, Policy, and/or Military Doctrine based on the findings from this pilot study. Funding for a larger follow-on study "Microcurrent Therapy for Chronic Low Back Pain," Principal Investigator COL Ann Nayback-Beebe, has been awarded by the TriService Nursing Research Program, Grant HU0001-16-1-TS10 (N16-P05), based on these pilot study findings.

Summary of Dissemination

Type of Dissemination	Citation	Date and Source of Approval for Public Release
Publication in Development	Nayback-Beebe, A., Yoder, L., Arzola, S., Weidlich, C., Inman, A., Goff, B. Effect of adjunctive pulsed electromagnetic frequency therapy on self-reported physical and mental health-related quality of life: A pilot study of service members with chronic low back pain. *Nursing Outlook* TSNRP 25th Anniversary Edition, In development. Publication pending Spring 2017	Pending
Published Abstracts	Nayback-Beebe, A., Arzola, S., Glaser, D., Simmons, A., Weidlich, C., & Goff, B. (2016). The effect of adjunctive pulsed electromagnetic frequency therapy on chronic low back pain symptom in active duty military: A pilot study [Abstract]. *Journal of Alternative and Complementary Medicine*, ahead of print. doi:10.1089/acm.2016.29003	BAMC CNSCI, DCI, & PAO approval on 10/26/15
	Arzola, S., McConnell, K., Serio-Melvin, M., Landt, C., Rauschendorfer, C., Nayback-Beebe, A., Gaylord, K., Smith, K., Ashley, J. (2013). Complementary & integrative medicine (CIM) devices: The relaxation effect on burn center staff [Abstract]. *Journal of Burn Care & Research*, 34(Suppl.1), 197.	BAMC CNSCI, DCI, & PAO approval on 9/21/12

Podium Presentations	Effect of Adjunctive Pulsed Electromagnetic Frequency Therapy on Self-Reported Physical and Mental Health-Related Quality of Life: A Pilot Study of Service Members with Chronic Low Back Pain. Podium presentation at the 2016 TriService Nursing Research Program (TSNRP) Course in San Antonio, TX. Authored by Nayback-Beebe, A., Arzola, S., Glaser, D., Weidlich, C., & Goff, B. Presented by Nayback-Beebe, A.	BAMC CNSCI, DCI, & PAO approval on 08/03/16
	The Effect of Adjunctive Pulsed Electromagnetic Frequency (PEMF) Therapy on Chronic Low Back Pain Symptom Severity and Disability In Active Duty Military Service Members: A Pilot Study. Podium presentation at the 2015 TriService Nursing Research Program (TSNRP) Course in San Antonio, TX. Authored by Nayback-Beebe, A., Arzola, S., Glaser, D., Simmons, A., & Goff, B. Presented by Nayback-Beebe, A.	BAMC CNSCI, DCI, & PAO approval on 06/18/15

FBCH PAO 06/17/15 |
| Poster Presentations | The Effect of Adjunctive Pulsed Electromagnetic Frequency Therapy on Chronic Low Back Pain Symptom In Active Duty Military: A Pilot Study. Poster presentation at the 2016 Military Health System Research Symposium (MHSRS) in Kissimmee, FL. Authored by Nayback-Beebe, A., Arzola, S., Glaser, D., Simmons, A., Weidlich, C., & Goff, B. Presented by Nayback-Beebe. | BAMC CNSCI, DCI, & PAO approval on 06/30/16 |
| | The Effect of Adjunctive Pulsed Electromagnetic Frequency Therapy on Chronic Low Back Pain Symptom In Active Duty Military: A Pilot Study. Podium presentation at the 2016 Integrative Medicine & Health Conference (IMHC) in Las Vegas, NV. Authored by Nayback-Beebe, A., Arzola, S., Glaser, D., Simmons, A., Weidlich, C., & Goff, B. Presented by Nayback-Beebe, A. & Arzola, S. | BAMC CNSCI, DCI, & PAO approval on 04/14/16 |

	The Effect of The Biomodulator on The Biopsychosocial Secondary Sequelae of Chronic Low Back Pain In Active Duty Military Service Members. Poster presentation at the 2015 SAMHS and Universities Research Forum (SURF) in San Antonio, TX. Authored by Nayback-Beebe, A., Arzola, S., Glaser, D., Feider, L., Simmons, A., & Goff, B. Presented by Nayback-Beebe, A. & Arzola, S.	BAMC CNSCI, DCI, & PAO approval on 07/14/15
	The Effect of The Biomodulator on The Biopsychosocial Secondary Sequelae of Chronic Low Back Pain In Active Duty Military Service Members. Poster presentation at the 2014 TSNRP Research and EBP Dissemination Course in San Antonio, TX. Authored by Nayback-Beebe, A., Arzola, S., Glaser, D., & Feider, L. Presented by Nayback-Beebe, A.	BAMC CNSCI, DCI, & PAO approval on 06/17/14

Reportable Outcomes

Reportable Outcome	Detailed Description
Applied for Patent	N/A
Issued a Patent	N/A
Developed a cell line	N/A
Developed a tissue or serum repository	N/A
Developed a data registry	N/A

Recruitment and Retention Table

Recruitment and Retention Aspect	Number	
Subjects Projected in Grant Application	75	
Subjects Available	unknown	
Subjects Contacted or Reached by Approved Recruitment Method	229	
Subjects Screened	84	
Subjects Ineligible	9	
Subjects Refused	0	
Human Subjects Consented	75	
Subjects Usual Care + PEMF / Usual Care only Group	39	36
Subjects Usual Care + PEMF / Usual Care only Group Who Withdrew	10	8
Subjects UC + PEMF / UC only Group Who Completed Study	29	28
Subjects UC + PEMF / UC only Group With Complete Data	29	28
Subjects UC + PEMF / UC only Group With Incomplete Data	0	0

UC = Usual Care; PEMF = Pulsed Electromagnetic Frequency;

Demographic Characteristics of the Sample

Characteristic	n=75
Age (yrs)	38.61±8.89
Women, n (%)	23 (30.7)
Race	
White, n (%)	46 (61.3)
Black, n (%)	9 (12.0)
Hispanic or Latino, n (%)	14 (18.7)
Native Hawaiian or other Pacific Islander, n (%)	0 (0.0)
Asian, n (%)	2 (2.7)
Other, n (%)	4 (5.3)
Military Service or Civilian	
Air Force, n (%)	11(14.7)
Army, n (%)	63 (84.0)
Marine, n (%)	0(0.0)
Navy, n (%)	1 (1.3)
Civilian, n (%)	n/a
Service Component	
Active Duty, n (%)	67(89.3)
Reservist on Active Duty Status, n (%)	2(2.7)
National Guard on Active Duty Status, n (%)	6(8.0)
Reserve, n (%)	n/a
National Guard, n (%)	n/a
Retired Military, n (%)	n/a
Prior Military but not Retired, n (%)	n/a
Military Dependent, n (%)	n/a
Civilian, n (%)	n/a

Program Budget Summary Report

Contract: 10248 - A Pilot Study Examining the Efficacy of Biomo
Award Amount: 351,264.00
Total Estimated: 351,264.00
Total Funded: 351,264.00

Contract PoP: 3/1/2012 - 8/31/2016
Customer: TRISERVICE NURSING RESEARCH PROGRAM
Customer Contract ID: HT9404-12-1-TS02
Contract Manager: Robinson, Kathleen

Category	Budget	Period	Cumulative	Commitments	Cumul. + Commit.	Remaining Balance
Direct Expenditures						
Personnel						
Personnel Salary & Wages	229,878.90	227,460.84	227,460.84	0.00	227,460.84	2,418.06
Fringe Benefits (Burden)	0.00	2,418.06	2,418.06	0.00	2,418.06	-2,418.06
Total Personnel	**229,878.90**	**229,878.90**	**229,878.90**	**0.00**	**0.00**	**0.00**
Non-Personnel						
Equipment	0.00	0.00	0.00	0.00	0.00	0.00
Travel	9,227.77	9,227.77	9,227.77	0.00	9,227.77	0.00
Supplies	38,119.05	38,119.05	38,119.05	0.00	38,119.05	0.00
Other	21.18	21.18	21.18	0.00	21.18	0.00
Consultant	6,825.00	6,825.00	6,825.00	0.00	6,825.00	0.00
Subcontractor Salary & Wages	0.00	0.00	0.00	0.00	0.00	0.00
Subcontractor Other	2,881.34	2,881.34	2,881.34	0.00	2,881.34	0.00
Total Non-Personnel	**57,074.34**	**57,074.34**	**57,074.34**	**0.00**	**57,074.34**	**0.00**
Total Direct Expenditures	**286,953.24**	**286,953.24**	**286,953.24**	**0.00**	**286,953.24**	**0.00**
Indirect Expenditures						
G&A Burden	60,083.00	53,538.45	53,538.45	0.90	53,539.35	6,544.12
Other Indirect Costs	4,632.62	0.00	0.00	0.00	0.00	4,632.62
Total Indirect Expenditures	**64,715.62**	**53,538.45**	**53,538.45**	**0.90**	**53,539.35**	**11,176.74**
Total Dir. + Indir. Expenditures	**351,668.86**	**340,491.69**	**340,491.69**	**0.90**	**340,492.59**	**11,176.74**
Fee Amount	0.00	0.00	0.00	0.00	0.00	0.00
Total Expenditures + Fee	**351,668.86**	**340,491.69**	**340,491.69**	**0.90**	**340,492.59**	**11,176.74**